

## **REMARKS**

### **I. The Office Action**

Claims 18-35 are currently pending. The Office maintained the rejection of claims 18-25 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent 5,260,282 (“Attstrom”) taken in view of International Patent Publication WO 93/16707 (“O’Mullane”), and extended the rejection to claims 26-35. Reconsideration of the rejection is respectfully requested.

### **II. The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn.**

Claims 18-35 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious in view Attstrom taken in view of O’Mullane. This rejection is traversed for the reasons set forth below.

In the Office Action, the Office clarified that the primary reference of the rejection is Attstrom. Attstrom teaches the use of an *aqueous* linseed extract to treat xerostomia (i.e., dry mouth). In contrast, the pending claims are directed to a method for the treatment of xerostomia (dry mouth) comprising administering a composition comprising a *solid, dried, water-soluble or water-dispersible* linseed extract. Attstrom provides no motivation for one of ordinary skill in the art to consider using a *dry* linseed extract; the entire teaching of Attstrom is directed to administering an *aqueous* solution. It is counter-intuitive to treat dryness of the mouth using a dry, solid product. Attstrom did not suggest this, and one of ordinary skill would certainly not have expected from Attstrom that a dry product would be an effective treatment for a dry mouth.

The Office acknowledged that Attstrom does not teach the use of a dried, solid product, but asserted that O’Mullane cures the deficiencies of Attstrom in this regard. However, due to the overwhelming teaching in Attstrom that an *aqueous* medicament is required, and the counter-intuitive nature of administering a dried extract to treat a dry mouth, one of ordinary skill would not combine the teaching of O’Mullane with that of Attstrom to treat xerostomia. The O’Mullane document pertains to preparation of linseed mucilage and formulations with another therapeutic agent. There is nothing in O’Mullane which specifically suggests that a linseed extract when used to treat dryness of the mouth should be

administered in a dried formulation. The mention of a lozenge on page 4 (cited by the Examiner) is only one of “a range of product presentations” listed, and xerostomia is *not* specifically listed in the paragraph. It should be noted that O’Mullane teaches that the native properties of O’Mullane’s linseed mucilage can be retained by combining it with gelling agents, and that its rheological properties “are retained on rehydration of dried mucilage” (see page 5, lines 5-16). In view of the teaching in the primary reference to use an aqueous extract and the teaching in the secondary reference that the desired rheological properties are retained on rehydration, it would have been unobvious to attempt to treat xerostomia with a dried extract as presently claimed. Instead, one of ordinary skill would follow the teachings of the primary reference because of the teachings that rehydrated extract retains its properties and the highly counterintuitive notion that dryness of the mouth could be better treated with a dry product.

The Office contends that there is a reasonable expectation that the dosage forms taught by O’Mullane would be successful when combined with the extract taught by Attstrom. Applicants respectfully disagree. First, one of ordinary skill would not consider using a dried extract to treat a dry mouth as “reasonable” upon reading Attstrom. Second, the extracts described in Attstrom and O’Mullane would not inherently display the adsorption characteristics required by the pending claims and, therefore, one of ordinary skill would not have believed that combining the references (even if there were a motivation to combine, which there is not) would yield predictable results. The Office asserted that the instant specification at page 16 teaches that the linseed extracts of Attstrom have the claimed adsorption characteristics. However, the Attstrom extract is an *aqueous* extract. If dried, the Attstrom extract would not inherently have the adsorption characteristics required by the pending claims, i.e., at least 1.2 mg/m<sup>2</sup>. Likewise, the O’Mullane extract would not inherently have the adsorption characteristics required by the pending claims. A range of adsorptions could be produced by drying linseed extracts, and there is nothing in the Attstrom or O’Mullane references suggesting that the surprisingly high adsorption level recited in the pending claims could be achieved.

Furthermore, the references, alone or in combination, do not teach or suggest the use of a spray-dried extract to treat xerostomia as recited in claim 20. The spray-dried

extract provides an unexpectedly high adsorption effect that could not be predicted from the prior art, as detailed in the specification at, e.g., page 16, paragraph 3, and the Figure.

The solid, dried linseed extract of the inventive method, in particular spray-dried linseed extract, has a surprisingly high adsorption level that could not be predicted from the prior art. The adsorption properties makes the solid, dried linseed extract of the inventive method particularly advantageous in the treatment of xerostomia. In addition to the improved adsorption seen for spray-dried extract, solid, dried linseed extract allows preparation of a convenient metered dose, with a discrete form of administration and less packaging than an aqueous product (see specification at page 5). These surprising advantages further support the non-obviousness nature of the claims.

In view of the above, the subject matter of claims 18-35 cannot be considered as obvious over the combination of Attstrom and O'Mullane, and the rejection under Section 103(a) should be withdrawn.

### III. Conclusion

In view of the above, Applicants submit that all outstanding rejections of the claims have been overcome, and the claims are in condition for allowance. The Examiner is invited to contact the undersigned attorney by telephone if there are issues or questions that might be efficiently resolved in that manner.

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Respectfully submitted,

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